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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,336	09/05/2000	Tomoko Ueda	1422-437P	9668

7590

04/03/2003

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EXAMINER
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WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/03/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/655,336

Applicant(s)

UEDA ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-18 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 9,10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,11,16-18 and 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15,16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted December 2, 2002 and December 12, 2002 is acknowledged.

#### ***Claim Rejections 35 U.S.C. 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 11, 16-18 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji et al. (JP 406100442) in view of Merck Manual (fifteenth edition) for reasons set forth in the prior office action. As to the newly added claims, which define the particular method for obtain the theanine employed in the composition, one of ordinary skill in the art would be motivated to employ isolated theanine insofar as the theanine is suitable for pharmaceutical or food purpose. Theanine obtained by different methods may be different in respect of the impurities contained therein. However, purifying a raw pharmaceutical composition, such as theanine composition, and making it suitable for pharmaceutical or food purpose is considered within the skill of artisan.

#### ***Response to the Arguments***

Applicants' amendments and remarks submitted December 2, 2002 and December 12, 2002 have been fully considered, they are persuasive in overcome the rejections under 35 U.S.C.

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102 and 112, but are not persuasive in respect with the above rejections for reasons discussed below.

Applicants argue that Merck Manual as cited by the examiner does not teach reduce stress is helpful in treating PMS. The examiner disagrees. As it well known, many of the symptoms of PMS are stress related, such as irritability, nervousness, lack of control, agitation etc. (see Merck Manual) Suppression or amelioration of any of the symptoms would meet the claimed limitation. And one of ordinary skill in the art would have been motivated to use a known anti-stress composition to PMS patient who need to suppress the stress. The examiner does not argue that the anti-stress composition would have been expected to suppress all the symptoms of PMS. Applicants' attention also directed to Merck Manual (p 1711) where it states that tranquilizers may be used for treating PMS patients.

How Fuji reference identifies the anti-stress activities of theanine is not relevant. Fuji teaches an anti-stress composition wherein theanine is the active ingredient. There is no limitation, teaching or suggestion that the anti-stress composition is merely useful for slowing heart rate or lowering blood pressure. One of ordinary skill in the art would use Fuji's composition as an anti-stress composition.

As to the concept of stress, following is a definition of "stress" in Dorland's Illustrated Medical Dictionary: "the sum of the biological reactions to any adverse stimulus, physical, mental, or emotional, internal or external, that tend to disturb the organism's homeostasis." PMS is a biological reaction to internal stimulus.

No claim is allowed.

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2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

SHENGJUN WANG  
PATENT EXAMINER  
S. ✓

Examiner

3-28-03